



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,170	07/16/2003	John Jacob Vander Zanden	3038	2206

7590 11/17/2005

WALTER A. HACKLER, Ph.D.
PATENT LAW OFFICES
SUITE B
2372 S.E. BRISTOL
NEWPORT BEACH, CA 92660-0755

EXAMINER

GEHMAN, BRYON P

ART UNIT PAPER NUMBER

3728

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,170

Applicant(s)

ZANDEN ET AL.

Examiner

Bryon P. Gehman

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 8-9 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Urheim (4,958,736). Urheim discloses a package for enabling compliance with a regimen of dosage of medication over a period of time, the package comprising a backing (16) having an array of receivers (12) including columns and rows, a plurality of sets of tablets (21 and 23), each tablet in a set having a common dose of the medication (in tablets 21, a dose of pharmacologically active contraceptive and in tablets 23, a total lack of the medication), each set being disposed in receivers of one of an adjacent row and an adjacent column, and indicia (18, 20) disposed adjacent the columns and rows for displaying common days and successive weeks.

As to claims 2 and 9, different sets of tablets are disposed in different rows (one set in rows 1-3, another in row 4), each row indicated as a successive week and each column indicated as a different day of the week.

As to claim 17, to merely provide the package is disclosed.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5-6, 8-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urheim in view of Lerner (3,568,828). Urheim discloses a package for enabling compliance with a regimen of dosage of medication over a period of time, the package comprising a backing (16) having an array of receivers (12) including columns and rows, a plurality of tablets (21 or 22) and indicia (18, 20) disposed adjacent the columns and rows for displaying common days and successive weeks. Lerner discloses it was known to provide tablets of different dosages at different times in the course of a regimen (see the Abstract and column 1, lines 42-54). To modify the package of Urheim employing tablets of different dosages would have been obvious in view of Lerner, because it was known to employ a controlled variable or pulsed release system in the birth control regimen field as disclosed by Lerner.

As to claims 2 and 10, Urheim discloses each row as a successive week and each column as a different day.

As to claims 5-6 and 13-14, to provide the alternative of the rows being days and the columns being weeks would have been an obvious modification of Urheim to one of ordinary skill in the art.

5. Claims 1-3, 5-6, 8-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0852208 in view of one of Urheim and CA 2,218,470. EP 0852208 discloses it was known to provide tablets of different dosages at different times in the course of a regimen (see the Abstract). Urheim and CA 2,218,470 each disclose

a package for enabling compliance with a regimen of dosage of medication over a period of time, the package comprising a backing (16; 10; respectively) having an array of receivers (12; 8) including columns and rows, a plurality of tablets (21 or 22; 12) and indicia (18, 20; 2 and as shown) disposed adjacent the columns and rows for displaying common days and successive weeks. To modify the regimen structure of EP 0852208 employing a single backing with receivers and indicia as disclosed by either one of Urheim and CA 2,218,470 would have been obvious in view of either Urheim or CA 2,218,470, because it would reduce the number of packages needed.

As to claims 2 and 10, Urheim and CA 2,218,470 each disclose each row as a successive week and each column as a different day.

As to claims 5-6 and 13-14, to provide the alternative of the rows being days and the columns being weeks would have been an obvious modification of either Urheim or CA 2,218,470 to one of ordinary skill in the art.

6. Claims 4, 7, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the art as applied to claims 3, 6, 11, 15 and 18 above, and further in view of Lipton (5,747,545). To employ memantine in a gradually increasing dosage to treat glaucoma to reduce damage to retinal ganglion cells was known in the medical field as taught by Lipton (see column 13, lines 28-55 and columns 19-24). To provide memantine in a controlled variable or pulsed release system of increasing dosages would have been obvious in order to ease the patient onto the medication to achieve systemic tolerance. The exact amounts of memantine employed would have been

Art Unit: 3728

dosages recognized as effective by one of ordinary skill in the art (a medical professional or pharmacist).

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Urheim in view of Lerner. To merely provide the package of the previously described combination would have been obvious in order to obtain the package advantages previously described.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03896 in view of one of Urheim and CA 2,218,470. To merely provide the package of the previously described combination would have been obvious in order to obtain the package advantages previously described.

9. Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0852208 in view of either one of Urheim and CA 2,218,470, and further in view of Lipton. The prior art combination has been explained above with respect to the package. To employ the package in the expected package manner to treat a patient to reduce damage to the retinal ganglion cells caused by glaucoma would have been obvious in view of EP 0852208, one of Urheim and CA 2,218,470, and Lipton, taken together.

10. Applicant's arguments with respect to claims 1-25 have been considered but are not deemed persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The package construction is clearly disclosed as known by Urheim or CA 2,218,470 in the medication regimen field, in Urheim specifically a contraceptive regimen. Lerner and EP 0852208 disclose it was known to vary the dosage of a medication during the course of a medication regimen, in Lerner specifically contraceptive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it has been shown that to construct a medication package with indicia pertaining to days and weeks as claimed was previously known in the field. It has been shown that to provide medication in different doses in the course of a regimen was known in the field. The applicants' structure and that what was known in the field would appear to be encompassed by general knowledge in the medication package field.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Monday through Wednesday from 5:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/622,170
Art Unit: 3728

Page 8

A handwritten signature in black ink, appearing to read "Bryon P. Gehman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Bryon P. Gehman
Primary Examiner
Art Unit 3728

BPG